

K961182

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510(K) SUMMARY
July 1, 1996

COMPANY NAME AND ADDRESS

Vista Medical Technologies
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CONTACT PERSON

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DEVICE TRADE NAME

3D SCOPE™

COMMON NAME

Laparoscopic Video System

PREDICATE DEVICE

1. Device Name: 3D Scope Three Dimensional Medical Video System
Classification: Camera, Television, Endoscopic, without audio
Manufacturer: American Surgical Technologies
300 Billerica Rd
Chelmsford, MA 01824
510(k) #: K923160

DEVICE DESCRIPTION

This 510(k) submission is for the addition of an indication for use of the currently marketed, cleared device 3D SCOPE™ Three Dimensional Medical Video System. 510(k) #: K923160. The primary application cleared for the AST 3D SCOPE™ is general endoscopic surgery and laproscopic procedures. This includes general thoracic procedures.

This submission is to add to the indications for use: examination of the evacuated cardiac chambers.

INTENDED USE

The 3D SCOPE™ is designed to aid in visualization for general endoscopic and laparoscopic procedures including general thoracic, and as an aid in visualization and examination of the evacuated cardiac chambers.

DEVICE COMPARISON

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The device is not modified in any way except for the added indication for use.